

§ 5.102 Authority to approve and to withdraw approval of a charge for investigational new drugs.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and the Office of Pharmaceutical Science, Center for Drug Evaluation and Research.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research.

(b) These officials may not further redelegate this authority.

§ 5.103 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355):

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research, for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act.

(b) The Directors and Deputy Directors of the divisions in the Offices of

Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or section 505(b)(2) of the act (21 U.S.C. 355 (b)(2)) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§ 314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For drug products listed in § 314.440(b) of this chapter and submitted under §§ 314.50, 314.70, and 314.94 of this chapter: The Directors and Deputy Directors, Office of Blood Research

and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in §§314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. (Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.)

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in §§314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §§314(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to ap-

prove supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in §5.10(a) and paragraphs (a) and (b) of this section.

(g) These officials may not further redelegate these authorities.

§ 5.104 Responses to Drug Enforcement Administration temporary scheduling notices.

The Director, Center for Drug Evaluation and Research (CDER) and the Director, Executive Operations Staff, Office of the Center Director, CDER, are authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under section 201(h)(4) of the Controlled Substances Act, as amended (21 U.S.C. 811(h)(4)). The delegation excludes the authority to submit reports to Congress. These officials may not further redelegate this authority.

§ 5.105 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in §314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Directors, Center for Biologics Evaluation and Research, for those drugs listed in §314.440(b) of this chapter, are authorized to issue notices of an opportunity